In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

GARY GIANNANTONIO, Parent of C.G., a minor,	*	
	*	No. 18-497V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: February 1, 2023
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement, diagnosis, ADEM, varicella vaccine
Respondent.	*	

Phyllis Widman, Widman Law Firm, Northfield, NJ, for petitioner;
Althea Davis and Sarah Rifkin, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Gary Giannantonio alleges that a varicella vaccine given to his daughter, C.G., caused her to suffer a neurologic problem, known as acute disseminated encephalomyelitis ("ADEM"). The Secretary disputed this allegation, contending that ADEM is not an appropriate diagnosis, and that Mr. Giannantonio has not shown that the varicella vaccine can cause ADEM. The parties developed their

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. This posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

positions by retaining experts who wrote reports and then arguing through legal memoranda.

Taken as a whole, the evidence does not preponderate in favor of finding that C.G. suffered from ADEM. The primary reason is that an MRI, which is a key piece of information for diagnosing ADEM, was normal. In addition, even if an ADEM diagnosis could be sustained, Mr. Giannantonio's evidence regarding how a varicella vaccine could cause ADEM was not sufficiently developed to be persuasive. Accordingly, Mr. Giannantonio is not entitled to compensation.

I. Facts

A. Early Medical History, including Vaccination

C.G. was born in 2007. Exhibit 1. Her family history included a grandmother with Sydenham's chorea and a paternal cousin with lupus. Exhibit 5 at 11. From birth to age eight years, C.G. periodically saw a pediatrician, Melissa Davidson, for routine medical care and typical childhood illnesses. See Exhibit 4, passim.[2] During this time, C.G. received a first dose of the varicella vaccine. Exhibit 4 at 18 (Sept. 9, 2009).

As an eight-year-old, C.G. had a well-child exam on April 8, 2005. Exhibit 4 at 1 (original), 40 (transcribed). Dr. Davidson assessed her as well. Id. C.G. received the allegedly causal varicella vaccine during this appointment. Id. at 18.

B. Potential Streptococcal Infection and Onset of Neurological Problems

On April 27, 2015, a Monday, C.G. returned to Dr. Davidson's office. The chief complaint was fever, which was recorded as 102 degrees. Exhibit 4 at 1, 40. Another notation states "tonsils inject, sore throat." Id. at 40. Histories taken by other doctors indicate that C.G.'s illness started on Sunday, April 26, 2015. See Exhibit 7 at 1; Exhibit 3 at 25 (Dr. Gliksman's note created on May 1, 2015), at 22-24 (Dr. Piwoz's note created on May 1, 2015). Dr. Davidson's impression was

[2] A portion of Dr. Davidson's records was filed as exhibit 26 (original records) and exhibit 27 (transcribed records). However, neither exhibit 26 nor exhibit 27 contain records from the critical time, April 2015. Therefore, this decision cites exhibit 4 as a source of information from Dr. Davidson.

to rule out strep throat. Exhibit 4 at 40. The rapid strep was negative and the throat culture was pending. Exhibit 4 at 40; see also Exhibit 7 at 4.

On April 28, 2015, a staff member spoke with C.G.'s mom, who said C.G. was lethargic and sleeping a lot. Exhibit 4 at 41. The doctor's office advised her mother to give her fluids and to update the office in the afternoon. Id.

Another entry from April 28, 2015 states: "equivocal T/C [throat culture] re-incubate, Duricef."[3] Id. Dr. Davidson's record contains additional details about the dose of Duricef and later records show that C.G. took this antibiotic. Exhibit 7 at 4 ("Patient has taken four doses of Cephalosporin"). On April 29, 2015, a staff member spoke to C.G.'s father about a positive throat culture. Exhibit 4 at 41.[4]

At approximately 10:00 P.M. on Saturday, April 30, 2015, C.G.'s parents brought her to an emergency room at Holy Name Medical Center ("Holy Name"). Exhibit 7 at 1. The chief complaint was "Recently diagnosed with strep, difficulty controlling fever, stating vision disturbance, gait disturbance, poorly tolerating [oral intake], complaining that pupils are very dilated." Id. On exam, the doctor assessed C.G. as "ill-appearing" and "irritable." Id. at 4. Under neurologic, the doctor found that C.G. had "increased tone in all four extremities, … mild slurred speech and slow to respond, wide based ataxic gait." Id. The doctors considered performing a spinal tap but deferred due to C.G.'s unstable condition. Id. at 5. Because the spinal tap was not done, the doctors decided to delay starting steroids, which would have been a treatment for ADEM. Id. The doctors obtained an additional throat culture, and the results were negative. Id. at 9. The doctor prescribed ceftriaxone and vancomycin. Id. at 2.[5]

The doctors at Holy Name decided to transfer C.G. to an institution offering higher care, Hackensack University Medical Center ("Hackensack"), which includes a pediatric intensive care unit. Exhibit 7 at 5. The Holy Name transfer

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[3] Duricef is an antibiotic. Dorland's Illus. Med. Dictionary (33 ed. 2012) at 567 (listing Duricef as a trademarked name for cefadroxil) & at 306 (defining "cefadroxil").

[4] Dr. Davidson's records do not include the results from any laboratory that tested any throat culture.

[5] Ceftriaxone is a third-generation antibiotic. Dorland's at 307. Vancomycin is an medication highly effective against staphylococci. Dorland's at 1993.

form indicates that the diagnoses on discharge from Holy Name included: "AMS [altered mental state], ataxia, ADEM." Exhibit 3 at 7. The transfer occurred shortly after midnight on May 1, 2015. Exhibit 7 at 13 (last entry: 05/01/15 00:43).

C. Hackensack University Medical Center PICU

C.G. arrived at 1:15 A.M. Exhibit 3 at 31 (nurse's note). At approximately 2:00 A.M., Dr. Shira Gertz obtained a history, which is more or less consistent with the history recorded above. Exhibit 3 at 16. Dr. Gertz's diagnoses were "altered mental status" and "strep pharyngitis." Id. Dr. Gertz prescribed or continued several medications, including acyclovir, azithromycin, vancomycin, and ceftriaxone. Id. at 18. It appears that Dr. Gertz ordered a lumbar puncture to look for an infectious source, although this portion of the medical record is difficult to read. Id. at 19. Dr. Gertz also ordered an MRI and a video EEG. Id.

The lumbar puncture was performed at approximately 3:00 A.M. on May 1, 2015. Exhibit 3 at 27, 31, 86. The tap was "bloody." Id. As such, the amount of protein, which exceeded 600 (Exhibit 3 at 87), was inconclusive. See Exhibit A at 2. The varicella zoster virus was not detected in the spinal fluid. Exhibit 3 at 89-90.

The chief of the section of pediatric infectious diseases, Julia Piwoz, saw C.G. at approximately 10:00 A.M. Exhibit 3 at 20, 25. The history, again, is mostly consistent with the information presented above. Dr. Piwoz's history adds that around the time C.G.'s strep test was negative, C.G. "did not have a sore throat and her mother does not feel they were told her throat was red." Id. at 20. After reviewing C.G.'s systems and examining her, Dr. Piwoz assessed C.G. as follows: "Doubt this is related to GAS [group A streptococcus] infection as her symptoms were not consistent with strep throat and she did not improve with treatment. Given the progression of her symptom[s], agree that there is a significant concern for ADEM. As such, I do not see a contraindication for giving steroids pending results." Id. at 24. Dr. Piwoz recommended several actions, including continuing the medications, obtaining an MRI, and consulting a pediatric neurologist. Id. Through the electronic medical records, Dr. Piwoz learned a few hours later that the rapid strep test from Holy Name was negative. Id. at 32.

The pediatric neurologist to whom Dr. Piwoz referred, Felicia Gliksman, saw C.G. in the morning of May 1, 2015. C.G. informed Dr. Gliksman that she had a headache and that she could see only the outline of objects. Exhibit 3 at 25. Dr. Gliksman identified problems with how C.G. moved both eyes. Id. at 26. Dr.

Gliksman assessed C.G. as an eight-year old "female with altered mental status, fever, ophthalmoplegia, and other CNS abnormalities which makes this highly suspicious for ADEM, though rarely seen with strep infections." Id. at 29. Dr. Gliksman indicated that the antibiotics the specialist in infectious disease ordered should be continued. Id. Dr. Gliksman also ordered an MRI and EEG. Id.

The EEG was performed shortly before noon. Exhibit 3 at 33. The EEG was "abnormal" "due to the presence of diffuse slowing. This is indicative of a diffuse cerebral dysfunction." Id. at 10.

An MRI with and without contrast was performed in the afternoon of May 1, 2015. The radiologist interpreting the results, Dr. Sudha Ramachandran, found that "some sequences are limited by motion." Exhibit 3 at 94. Dr. Ramachandran also found "a focal area of T1 hypointensity in the upper cervical spine at the C2 level, which could be artifactual." Id. The conclusion was: an "unremarkable MRI of the brain with and without contrast." Id.

A May 2, 2015 note from Dr. Gliksman incorporated the MRI findings. Exhibit 3 at 41. When Dr. Gliksman examined C.G., Dr. Gliksman continued to find eye and vision problems. Id. at 42. Dr. Gliksman's summary included both "MRI brain normal and EEG diffuse slowing." Id. at 45. Dr. Gliksman indicated a diagnosis was "likely viral encephalitis." Id. Dr. Gliksman's plan included reviewing the MRI with radiology again to see whether the orbits were well visualized. Id. at 46.

Dr. Gliksman documented that she "reviewed MRI brain again with neuroradiology (Dr. Patel). No evidence of abnormality seen in orbits on this study but obviously not a dedicated study." Id. Dr. Gliksman also commented on the results of the spinal tap: "Cervical cord finding likely artifact as it does not explain the altered mental status, eye findings, and ataxia." Id.

On May 3, 2015, a team of doctors at Hackensack reviewed C.G.'s case. Martha Kutko, an attending doctor in the pediatric intensive care unit, reported that C.G. had "encephalitis, likely post infectious." Exhibit 3 at 53. Dr. Kutko indicated that C.G. "received the Varivax vaccine ~ 3 weeks ago. Adverse vaccine reaction would have occurred within 1-2 weeks as discussed with Dr. Piwoz." Id. at 54. Based upon a discussion with Dr. Gliksman, Dr. Kutko changed the steroid that C.G. was receiving from methylprednisolone to prednisone. Id. Dr. Kutko also reported that the family wanted C.G. transferred to another hospital. Id.

The May 3, 2015 progress note authored by Dr. Piwoz added details. Dr. Piwoz described C.G. as a "female with symptoms suggestive of ADEM, responding well to steroids. She is having emotional lability common for this dose of steroids." Id. at 51. Dr. Piwoz discontinued some anti-infectious medications as testing for those organisms were negative. See id. at 62. With respect to acyclovir, Dr. Piwoz stated it could be stopped because "this is not a result of direct viral invasion but likely an immune-mediated response." Id. at 51. Dr. Piwoz added that she advised Dr. Davidson to file a VAERS report. Id.; see also Exhibit 4 at 41 (Dr. Davidson's record reflecting a conversation among Dr. Kutko, Dr. Piwoz, and herself). While Dr. Davidson submitted a VAERS report, the report, itself, memorializes a sequence of events based upon the information available on the date the report was submitted, May 4, 2015. Exhibit 6.

The pediatric neurologist, Dr. Gliksman, modified her assessment on May 3, 2015. Dr. Gliksman reported: "Yesterday evening, the PMD [private medical doctor] reported that she received Varivax booster 3 weeks ago." Exhibit 3 at 67. In her assessment, Dr. Gliksman wrote: "BASED ON NEW INFO FROM PMD, MOST LIKELY THAT SHE HAS AN IMMUNE MEDIATED POLYNEUROPATHY AND less likely viral encephalitis although cannot fully discount." Id. at 71. Dr. Gliksman discontinued steroids because C.G. was "not having much improvement and having hallucinations" and Dr. Gliksman started intravenous immunoglobulin ("IVIG") due to a "lack of substantial neurological improvement." Id.

In preparation for being transferred, C.G. was moved out of the pediatric intensive care unit. On the general floor, she received a dose of IVIG. Exhibit 3 at 61; see also id. at 66.

A discharge report was written at 5:30 P.M. on May 3, 2015. Id. at 60-63. The final diagnosis was identified as "Altered mental status." Id. at 60. The discharge report states that C.G.'s course "seemed more consistent with [an] immune mediated response, and less likely viral encephalitis. Considering this, steroids were also discontinued in favor of IVIG for combating and hopefully alleviating the immune mediated response." Id. at 62.

D. Children's Hospital of New York

The report on admission appears largely based upon the Hackensack discharge report. See Exhibit 5 at 9-11. The doctor responsible for the attending section was James Riviello. Dr. Riviello summarized C.G.'s case as an "acute onset of an apparent streptococcal illness with then irritability, visual complaints,

and ataxia, initially diagnosed as ADEM but with a normal MRI, LP negative for infection but had been pre-treated with antibiotics, then recei[]ved steroid[s] and IVIG because she was not improving as quickly as everyone wanted." Id. at 11. Dr. Riviello planned to send "more studies to assess for an immune reaction, likely from strep, although she has received IVIG, which can alter the findings." Id. Dr. Riviello also anticipated coordinating care with neurology and ophthalmology. Id.

Late in the afternoon on May 4, 2015, two ophthalmologists, Dov Sebrow and Steven Brooks, the attending physician, saw C.G. The history states that the differential diagnosis "includes ADEM due to acute onset of mental status changes, but is less likely given a negative MRI. Of note she received Varivax 3 weeks prior to presentation. Still in the differential is also a viral encephalitis, or post-infectious syndrome." Exhibit 5 at 13. Dr. Sebrow, who primarily wrote the report, indicated that C.G. had poor vision and other eye problems. These problems as well as ataxia and a hearing deficit "may be 2/2 [secondary to] viral/post infectious encephalitis." Id. Dr. Sebrow and Dr. Brooks did not recommend any ophthalmologic intervention.

A pediatric neurologist, Jennifer Bain, saw C.G. in consultation with Dr. Riviello on May 5, 2015. Dr. Bain described C.G. as having an "acute onset encephalopathy . . . preceded by strep pharyngitis." Id. at 17. Dr. Bain ordered more laboratory studies, requested a consultation with an audiologist, and planned to "review OSH [probably "outside hospital"] imaging with neuroradiology." Id.[6] One of the labs showed that ASO and DNASE B antibodies were normal in a sample collected on May 4, 2015. Id. at 3, 52.

The ophthalmologist, Dr. Sebrow, again saw C.G. on May 5, 2015. Dr. Sebrow's examination showed that C.G. was "mildly improved and less dilated today compared to [yesterday's] exam." Exhibit 5 at 19. Dr. Sebrow repeated his concern that C.G. could have "viral/post infectious encephalitis." He added that it could also be the "Miller-Fisher variant." Id.

[6] It appears that personnel at Children's Hospital of New York did not review the outside imaging directly as there is no notation of this happening. In addition, the discharge report states: "LAST EEG: reportedly normal OSH" and "LAST MRI: reported normal OSH." Exhibit 5 at 52.

An audiologist, Fran Shapiro, tested C.G. on May 6, 2015. The results showed "mild to moderately severe sensorineural hearing loss" in both ears. Id. at 27.

A different pediatric neurologist, Lauren Dunn, evaluated C.G. with Dr. Riviello on May 6, 2015. Dr. Dunn found that C.G. was "improving slowly." Exhibit 5 at 35. Like Dr. Sebrow, Dr. Dunn was concerned about the "Miller Fisher variant of GBS." Id. Dr. Dunn's summary the following day was similar. Id. at 39.

For the May 8, 2015 pediatric neurology daily progress report, Dr. Riviello added that he spent "15 minutes [] counseling regarding the diagnosis of likely Miller-Fisher Syndrome, the therapeutic [options] and that we shall not give any subsequent immune-mediated therapy if she continues to improve." Id. at 43. A May 10, 2015 report from Dr. Riviello was similar. Id. at 56.

C.G. was discharged from Children's Hospital of New York on May 11, 2015. Id. at 50. Dr. Riviello endorsed the report. Id. at 54. Dr. Riviello summarized that C.G. "has improved and [is] ready for transfer to rehabilitation." Id. at 53. He indicated a "tentative diagnosis of post-infectious disorder, [likely] Bickerstaff encephalitis versus Miller Fisher syndrome." Id.[7]

E. Remainder of 2015

After C.G. left Children's Hospital of New York, she went to a rehabilitation facility and periodically saw medical providers. Exhibit 22. However, only a few records contribute to evaluating the claim that the varicella vaccination caused C.G. to suffer ADEM. Thus, other records from 2015 are presented somewhat summarily.

In anticipation of returning to school, in September 2015, C.G.'s parents arranged for her to see a pediatric neuro-ophthalmologist, Steven Kane. Dr. Kane's ensuing report contains an impressive amount of details regarding her history. In recounting the events of April 2015 and May 2015, Dr. Kane stated: "Since the MRI results were reported normal, ADEM was considered less likely than a postinfectious or post-vaccination encephalitis. Miller-Fischer syndrome and Bickerstaff encephalitis were mentioned as possible bases but anti-GQ1b IgG

[7] When C.G. was discharged from the Children's Hospital of New York, a test for GQ1b antibodies was pending. Exhibit 5 at 52. On May 16, 2015, the result was reported as negative. Id. at 2.

antibodies were not found." Exhibit 11 at 2. Dr. Kane examined her and reported the extent of her visual trouble. He concluded: "These results recognize asymmetric acuities associated with bilateral optic neuropathy and atrophy in this child who developed para-infectious or immune encephalitis 4 months ago. Besides visual impairment residual deficits involve audition and cognition. Except for a lack of neuroimaging evidence the clinical course suggests acute disseminated encephalomyelitis with demyelination of the optic nerves." Id. at 3. With respect to diagnosis, Dr. Kruer ane added: "The conspicuous involvement of the anterior visual pathways and lack of anti- GQ1b IgG antibodies would seem to make the Miller-Fischer syndrome and Bickerstaff encephalitis unlikely explanations for her condition." Id. at 4. For a plan, Dr. Kane suggested obtaining a visually evoked potential and, possibly, another MRI. Id.

It appears that C.G.'s parents stopped taking her to her previous pediatrician, Dr. Davidson. See Exhibit 4 at 42 (noting the parents did not respond to requests for information). Instead, C.G.'s parents began seeking medical care for C.G. from Lawrence Rosen, a doctor at the Whole Child Center on October 20, 2015. Exhibit 24 at 41. Dr. Rosen recorded a history that included a diagnosis of "post infectious neuroimmune syndrome. . . . Sequelae include both visual and auditory impairment, due for hearing aids this month." Id. at 42. After examining her, Dr. Rosen assessed C.G. as having a "disorder of [the] brain," for which he suggested "complementary nutritional support." Id.

Based upon a referral from Dr. Rosen, C.G. started to see a pediatric neurologist, Wendy Vargas, on November 17, 2015. Exhibit 36 at 11-13. Dr. Vargas's report concludes: "Her MRI brain was normal. Her story is typical of postinfectious encephalitis, with development of neurologic symptoms days after febrile illness. However, her MRI is not typical of ADEM. . . . I would like to review [the] original MRI of the brain." Id. at 13. Dr. Vargas stated that because C.G. did not have a relapsing disorder, she did not need any immune therapy. Id. Dr. Vargas planned to see C.G. in six months. Id.

F. Records Created in 2016 to the Present

A much later record from Dr. Vargas, a record from October 29, 2019, states: C.G. had an "episode of encephalitis in close proximity to a varicella booster in April 2015. Her stability over the last 4 years and lack of new symptoms suggest that she has a monophasic course and her current vision and hearing issues are residual from her initial event." Exhibit 66 at 16. This comment indicates that the medical evaluations in the recent years tend not to inform a

resolution of the disputed issues. Nevertheless, a few records are relevant to determining whether the varicella vaccine caused C.G. to suffer ADEM.

Relevant records include the six-month follow up appointment with Dr. Vargas, which occurred on May 17, 2016. Exhibit 36 at 8. At this time, C.G. was having vision problems on her left side and hearing problems on both sides for which she was wearing hearing aids. Id. In anticipation of this appointment, Dr. Vargas personally reviewed the May 20, 2015 MRI. Id. at 10. Dr. Vargas stated that the MRI "is normal. There is some slight periventricular capping but this appears within the realm of normal to me." Id. at 10. Dr. Vargas commented: "I find it odd that her MRI brain was completely normal. I also find it odd that she has not recovered her vision or hearing more significantly." Id. In terms of a plan, Dr. Vargas recommended another MRI and referred C.G. to a geneticist. Id. The genetic testing was normal. Exhibit 66 at 7.

The repeat MRI happened on June 20, 2016 and produced a normal result. The interpreting radiologist stated: "Unremarkable MRI of the brain and orbit. Normal appearance of both orbits. Symmetric appearance of the 7th and 8th nerve complexes without evidence for mass or abnormal enhancement." Exhibit 36 at 20.

Despite medical treatment, C.G.'s problems persisted. In a November 24, 2020 report, Dr. Vargas stated that C.G.'s school went all virtual during the pandemic. Exhibit 66 at 8. Her vision and hearing were stable since the previous visit with Dr. Vargas. Id. Dr. Vargas and the family talked about the novel COVID 19 vaccines. Dr. Vargas indicated that "given her profound neurological impairment in the setting of Varivax, she should not receive further vaccinations." Id. at 12.

About one year later, Dr. Vargas reassessed C.G. and reconsidered the COVID vaccines. At this time, Dr. Vargas stated: "Although I worry given her prior history, I did cite a recent study looking at recurrent GBS in mRNA treated COVID vaccine patients. . . . While her diagnosis and clinical scenario are different, this study cites evidence that mRNA vaccines are safe even in those with

previous neurological autoimmune diseases. I would be happy to support her in either decision (to vaccinate or not)."[8] Exhibit 73 at 21 (Nov. 23, 2021).

II. Procedural History

Mr. Giannantonio initiated this case by filing a petition on April 4, 2018. He submitted medical records on various dates until he represented that the records were complete. Pet'r's Statement of Completion, filed July 6, 2018.

The Secretary reviewed this material and advised that Mr. Giannantonio was not entitled to compensation. Resp't's Rep., filed Sept. 17, 2018. The Secretary noted that many medical records were missing and requested that Mr. Giannantonio produce them. Id. at 14 n.10. The Secretary questioned the appropriate diagnosis for C.G., describing disagreements among her treating doctors. Id. at 16-17. The Secretary indicated that "some physicians considered an association between C.G.'s reports of a sore throat and fever and strep infection, but the reports of these symptoms were inconsistent." Id. at 17 (citations omitted).

After the Secretary identified many missing medical records, Mr. Giannantonio sought to obtain them. This process lasted more than one year. After Mr. Giannantonio filed multiple medical records, the Secretary found the record to be sufficient. Resp't's Status Rep., filed Jan. 6, 2020.

As C.G.'s medical records had been submitted, the next step was to obtain reports from experts. To facilitate this process, a set of Instructions was issued, first in draft form and then in final form. Order, issued Feb. 12, 2020.

Mr. Giannantonio produced a report from Georges A. Ghacibeh, a neurologist, on April 29, 2020. Exhibit 40. The Secretary submitted a report from Michael C. Kruer, a pediatric neurologist, on September 14, 2020. Exhibit A. A second round of reports was submitted on November 30, 2020 (Exhibit 49) and February 24, 2021 (Exhibit C). The parties periodically filed the articles on which their experts relied.

When the experts completed their written reports, the parties were directed to file briefs. Order, issued March 23, 2021. Mr. Giannantonio submitted his primary brief on July 26, 2021, and his reply brief on December 29, 2021. In

[8] Dr. Vargas relied upon Ben David et al., "Rate of Recurrent Guillain-Barré Syndrome After mRNA COVID-19 Vaccine BNT162b2" 78(11) JAMA Neurol. 1409 (2021).

between, the Secretary filed his brief on November 29, 2021. Mr. Giannantonio also took this opportunity to update the medical records about C.G. With the filing of Mr. Giannantonio's reply brief, the case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

IV. Diagnosis

In Broekelschen v. Sec'y of Health and Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence in the record before applying the Althen test." Here, the parties dispute two aspects of C.G.'s medical history. Preliminarily, there is a question about whether C.G. was infected with strep at the end of April 2015. More importantly, the parties disagree as to whether C.G. suffered ADEM.

A. Strep

To review, an initial strep test performed in Dr. Davidson's office was negative. But, a test on a throat culture returned a positive result and C.G. was placed on antibiotics. When she came to the emergency room, she had taken four doses of cephalosporin and in the Holy Name emergency room, her strep tests were negative. Exhibit 7 at 4, 9. Later, at the Children's Hospital of New York,

two tests that can detect strep were normal. Exhibit 5 at 3, 52 (ASO and DNASE B antibodies).

The positive result on the throat culture appears to be persuasive evidence that C.G. was infected with strep at the end of April 2015. Dr. Ghacibeh attempted to minimize this result by suggesting that the positive result was due to contamination. Exhibit 40 at 4; see also Pet'r's Br. at 2. However, the record does not contain any information about how often false positives appear. Thus, Dr. Ghacibeh's contention, although logically possible, seems unfounded.

Ultimately, resolving whether a preponderance of evidence supports a finding that C.G. did (or did not) have a strep infection appears unnecessary. The Secretary's opposition to compensation does not turn on the strep infection. For example, Dr. Kruer has not contended that a strep infection could have caused C.G.'s neurologic problems. See Exhibit A. In Dr. Kruer's first report, he only contended: "Although it is uncertain whether CG's streptococcal infection was directly related to her decline, the strep infection is the most plausible explanation for her fever." Id. at 3. Similarly, although the Secretary was offered a chance to argue that a factor unrelated to the varicella vaccine caused C.G.'s problems, order, issued Mar. 23, 2021, at 8, the Secretary did not advance this argument. See Resp't's Br. Accordingly, whether C.G. suffered a strep infection is not a material fact because its proof (or lack thereof) would not change the outcome of the case.

B. ADEM

On the other hand, whether C.G. suffered ADEM is a material fact. Mr. Giannantonio alleges that the flu vaccine caused C.G. to have ADEM. Pet'r's Br. at 4-5 (proposing diagnostic criteria for ADEM), at 10 ("C.G.'s varicella vaccine caused her to suffer from ADEM.").

An initial step in determining whether a vaccinee suffers from a condition is to review the diagnostic criteria for that condition. Instructions, issued on Jan. 28, 2020, ¶ 4.b, ("the expert should describe any relevant diseases, including the diagnostic criteria"); Order for Briefs, issued on Mar. 23, 2021, at 4, ("the parties should identify the diagnostic criteria for acute disseminated encephalomyelitis").

Here, Mr. Giannantonio has advanced a set of criteria from a website, which Dr. Ghacibeh did not endorse explicitly. Pet'r's Br. at 4. The footer at the bottom of the printed page indicates that the source of information is the website "wearesrna.org." Exhibit 68. By using quotation marks, Mr. Giannantonio states the website says:

> A first clinical attack of central nervous system demyelinating disease with acute or subacute onset, polysymptomatic neurologic features, and encephalopathy, encephalopathy [sic] as a presenting symptom, with the onset of encephalopathy corresponding with the occurrence of the disease state (encephalopathy is defined to include behavioral changes, such as lethargy or irritability, or severe changes in the level of consciousness such as coma). These features help distinguish ADEM from other clinically isolated syndromes.

Pet'r's Br. at 5. However, Mr. Giannantonio's quotation is not accurate. Citing the Krupp criteria for ADEM in children, the website actually states:

> The major criteria include:
>
> 1. A first clinical attack of central nervous system demyelinating disease with acute or subacute onset, polysymptomatic neurologic features, and encephalopathy
>
> 2. Brain MRI showing focal or multifocal lesions, predominantly involving the white matter, without evidence of previous white matter changes
>
> 3. Encephalopathy as a presenting symptom, with the onset of encephalopathy corresponding with the occurrence of the disease state (encephalopathy is defined to include behavioral changes, such as lethargy or irritability, or severe changes in the level of consciousness such as coma).

Exhibit 68 (Siegel Rare Neuroimmune Association, *Acute Disseminated Encephalomyelitis*, https://wearesrna.org/living-with-myelitis/disease-information/acute-disseminated-encephalomyelitis/diagnosis/ (last visited July 26, 2021) at 3). Mr. Giannantonio omits criterion 2, which refers to MRIs. This omission is significant because the website also states: "An MRI of the brain and spine is important to establish a diagnosis of ADEM." Id. at 2.

A consideration of MRI evidence is consistent with the diagnostic criteria on which Dr. Kruer relied. According to an international pediatric multiple sclerosis

study group, an "MRI typically shows diffuse, poorly demarcated, large, >1-2 cm lesions involving predominantly the cerebral white matter." Exhibit A-1 (Krupp et al., "International Pediatric Multiple Sclerosis Study Group criteria for pediatric multiple sclerosis and immune-mediated central nervous system demyelinating disorders: revisions to the 2007 definitions" 19(10) Multiple Sclerosis J. 1261, (2013)) at 1266 (Appendix 2). Special masters have relied upon the Krupp criteria. O.M.V. v. Sec'y of Health & Hum. Servs., No. 16-1505V, 2021 WL 3183719, at *1 (Fed. Cl. Spec. Mstr. June 16, 2021), mot. for rev. denied, 157 Fed. Cl. 376 (2021); Orloski v. Sec'y of Health & Hum. Servs., No. 17-936V, 2019 WL 7565495, at *9 (Fed. Cl. Spec. Mstr. Oct. 31, 2019), mot. for rev. denied, 147 Fed. Cl. 713 (2020), aff'd, 839 F. App'x 538 (Fed. Cir. 2021); Spracklen v. Sec'y of Health & Hum. Servs., No. 16-559V, 2019 WL 4201572, at *4-5 (Fed. Cl. Spec. Mstr. July 31, 2019).

The main point of controversy regarding diagnosis between Dr. Ghacibeh and Dr. Kruer concerns the usefulness of MRI's for C.G. C.G. underwent two MRIs, one on May 1, 2015 (exhibit 3 at 94) and a second on June 20, 2016 (exhibit 39 at 19). Both were essentially normal.[9]

According to Dr. Kruer, "a lack of demyelinating lesions on MRI is in fact incompatible with ADEM" as defined by the Krupp article. Exhibit A at 4. Dr. Kruer's opinion---that cases of ADEM will have a lesion on an MRI---is consistent with some doctors who treated C.G. Exhibit 5 at 11 (Dr. Riviello); Exhibit 36 at 11 (report from Dr. Vargas on Nov. 17, 2015). Because these doctors were treating C.G., their opinion warrants additional consideration. Cappizano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Nevertheless, Dr. Ghacibeh opines that the normal results on the May 1, 2015 MRI do not preclude a diagnosis of ADEM. In Dr. Ghacibeh's view, the MRI was done too quickly in the disease process in that the lesions may not have formed. Exhibit 49 at 2.[10] For support, Dr. Ghacibeh relies upon an article

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[9] The first MRI may have contained an artifact. However, a motion artifact "is quite common in pediatric MRI studies." Exhibit A (Dr. Kruer's report) at 4. Dr. Kruer, therefore, opined that the results were technically adequate. Exhibit A at 4.

[10] Dr. Ghacibeh also maintains that the June 20, 2016 MRI was done too late in the disease process because by this date, any lesions might have healed. Exhibit 49 at 3.

published in 2001 and written by Jari Honkaniemi and colleagues. Exhibit 42 (Jari Honkaniemi et al., "Delayed MR Imaging Changes in Acute Disseminated Encephalomyelitis," 22 Am. J. Neuroradiol. 1117 (2001)).

Dr. Kruer has persuasively shown that Honkaniemi provides little helpful information. As Dr. Kruer pointed out, this article was written in 2001. Since then, the magnets used in MRIs have gotten stronger, increasing the ability to detect lesions. Exhibit A at 4, citing Exhibit A, tab 2 (Birgit Simon et al., "Improved in vivo detection of cortical lesions in multiple sclerosis using double inversion recovery MR imaging at 3 Tesla," 20 Eur Radiol 1675 (2010)). For these reasons, the lack of demyelinating lesions on the MRI tends to support a finding that C.G. did not suffer from ADEM. O.M.V., 2021 WL 3183719, at *40 (noting one reason for finding against a diagnosis of ADEM was that petitioner's "MRIs were normal"); Rodriguez v. Sec'y of Health & Hum. Servs., No. 14-722V, 2019 WL 4055016, at *8 (Fed. Cl. Spec. Mstr. July 29, 2019) ("If M.R. had ADEM, the MRIs likely would have shown lesions regardless of whether contrast was used"); Spracklen, 2019 WL 4201572, at *5 ("the negative MRIs weigh strongly against the ADEM diagnosis").

In addition to a positive MRI, the Krupps group also determined that another criterion for an ADEM diagnosis was a "polyclonal, clinical CNS event with presumed inflammatory demyelinating cause." Exhibit A-1 (Krupp et al.) at 1262. Dr. Kruer opined that there is "no evidence of central nervous system inflammation." Exhibit A at 4. Thus, according to Dr. Kruer, this was a second way in which C.G.'s presentation did not fit the diagnostic criteria for ADEM.

In response, Dr. Ghacibeh pointed to C.G.'s ataxia, altered mental status, and optic neuritis as manifestations of neuroinflammation. Exhibit 49 at 2. Features such as altered mental status, ataxia, and pyramidal signs are "consistent with ADEM." Id. at 1.

The problem with Dr. Ghacibeh's response, as Dr. Kruer maintained, is that a symptom being "consistent with" a condition does not necessarily make the symptom diagnostic for the condition. These symptoms may be consistent with other conditions that do not involve inflammation. Resp't's Br. at 30. Mr. Giannantonio did not rebut this argument. See Pet'r's Reply.

On the specific point regarding whether C.G.'s presentation was consistent with inflammation in the central nervous system, each expert offers a plausible interpretation of C.G.'s medical records. But, resolving this narrow question is not

necessary. As indicated above, the lack of a demyelinating lesion undermines the diagnosis of ADEM.

While C.G. experienced an altered mental status, difficulty walking, problems with her visions, and, eventually, problems with her hearing, whether these symptoms amounted to ADEM befuddled her doctors. The doctors appeared to focus on treating these problems, rather than labeling her condition as "disease X" or "disease Y." See, e.g., Exhibit 3 at 60-63 (discharge report from Hackensack). The lack of clarity from the treating doctors does not help Mr. Giannantonio because, ultimately, he bears a burden of demonstrating, by preponderant evidence, that C.G. suffered from the disease a vaccine allegedly caused. See Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012) (inconclusive reports from treaters did not require special master to accept the diagnosis proposed in the litigation).

Some treaters entertained the possibility that C.G. suffered from ADEM. A prominent example is Dr. Gliksman, the pediatric neurologist who cared for C.G. during her hospitalization at Hackensack. In Dr. Gliksman's first report created on May 1, 2015, Dr. Gliksman indicated C.G.'s clinical presentation "which makes this highly suspicious for ADEM, though rarely seen with strep infections." Exhibit 3 at 29. A statement of suspicion is not the same as a diagnosis. More importantly, Dr. Gliksman presented her suspicion before C.G. underwent the MRI, which returned normal results. After Dr. Gliksman reviewed the MRI, the diagnosis was "likely viral encephalitis." Exhibit 3 at 45 (May 2, 2015). Then, after learning that C.G. had received a varicella vaccine three weeks before the onset of symptoms and after testing had not revealed the presence of any infectious organisms, Dr. Gliksman stated an "immune mediated polyneuropathy" was more likely and a viral encephalitis was less likely, although still possible. Id. at 71.

Dr. Gliksman is one example of how treaters considered multiple possible diagnoses for C.G. Another example is Dr. Riviello, who led the team of doctors caring for C.G. at Children's Hospital of New York. Before C.G. was discharged, Dr. Riviello indicated that she suffered from Miller-Fisher syndrome. Exhibit 5 at 43 (May 8, 2015 daily progress report), 53 (May 11, 2015 discharge report). However, doctors discarded Miller-Fisher syndrome after testing for GQ1b antibodies was negative. Exhibit 11 at 2.

When the treating doctors have not settled on a diagnosis, a petitioner may rely upon the report of a doctor retained in the litigation to establish, on a more likely than not basis, the condition affecting the vaccinee. Mr. Giannantonio has attempted to use Dr. Ghacibeh for this purpose. However, Dr. Ghacibeh's opinion

is not persuasive. As noted above, C.G.'s normal MRI would make a diagnosis of ADEM atypical. There is also little persuasive evidence that C.G. experienced inflammation in her central nervous system. To accept Dr. Ghacibeh's diagnosis would implicitly suggest that Dr. Gliksman and Dr. Riviello missed a diagnosis as they were caring for C.G. Dr. Ghacibeh has not persuasively shown that he is better positioned or better qualified than these two pediatric neurologists. See Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343, 1353-54 (Fed. Cir. 2011) (determining that special master was not arbitrary in refraining from crediting a diagnosis proposed by an expert in litigation that a treating neurologist did not offer).

For all these reasons, the evidence does not preponderate in favor of finding that C.G. suffered from ADEM. This finding means that Mr. Giannantonio is not entitled to compensation. Nevertheless, one Althen prong is considered.

V. Medical Theory

To prove causation-in-fact, petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). This theory must be persuasive. Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1356-57 (Fed. Cir. 2019). In assessing a theory, special masters may look for indicia of reliability. See Moberly, 592 F.3d at 1324.

From both experts, development of the theory how a varicella vaccine can cause ADEM was thin. Dr. Ghacibeh's first report discusses molecular mimicry for two paragraphs. Exhibit 40 at 5-6. Dr. Ghacibeh did not cite any articles in this section. Dr. Kruer's response was even shorter, contained in two sentences: "There is no evidence whatsoever of molecular mimicry, nor of T-cell mediated autoimmunity. There is no reliable evidence of a link between the varicella vaccine and T-cell mediated autoimmunity [or] ADEM." Exhibit A at 6.

In his second report, Dr. Ghacibeh strengthened his position by relying upon an article written by Zh. R. Idrissova and colleagues. Exhibit 49 at 4-5. In this article, the researchers identified 90 children who were diagnosed with ADEM in a hospital in Moscow between 1993 and 1999. Exhibit 52 (Idrissova et al. "Acute disseminated encephalomyelitis in children: clinical features and HLA-DR

linkage," 10 Euro. J. Neuro. 537 (2003)) at 537-38. They tested for various infectious organisms, such a varicella zoster, and based upon this testing, the researchers found 26 children "developed chicken pox 5-12 days before they presented neurological symptoms." Id. at 539. The researchers compared the clinical presentation associated with "varicella ADEM" with other conditions, such as "rubella ADEM." Idrissova and colleagues seem to omit any discussion of how varicella virus causes dysfunction in the central nervous system. At least two methods appear plausible: a direct viral invasion and an indirect autoimmune response.

Dr. Ghacibeh advanced the second method. He wrote: "In the case of the live Varicella vaccination, the mechanism is due to the auto-immune response caused by the live virus itself. . . . The Varicella virus, which is contained in the live vaccine, is known to cause the post infectious complication of demyelinating diseases such as ADEM." Exhibit 49 at 4.[11] Consistent with Dr. Ghacibeh's two reports, Mr. Giannantonio puts forward molecular mimicry.[12] The argument is contained in one page, citing a single article in this section.[13] Pet'r's Br. at 10.

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[11] Dr. Kruer seems to assume that Dr. Ghacibeh was putting forward a theory based upon a direct invasion. See Exhibit C at 3 ("An attenuated vaccine uses virus that does not have the same invasive potential that is required for direct invasion of central nervous system tissue.").

[12] Even if Mr. Giannantonio had established that the attenuated virus in the varicella vaccine can directly invade the central nervous system, and thereby meet a burden for Althen prong 1, Mr. Giannantonio would have difficulty establishing this happened to C.G. When her spinal fluid was tested on May 1, 2015, the varicella virus was not detected. Exhibit 3 at 89-90.

[13] Mr. Giannantonio cites a website to explain "antigenic characterization." Exhibit 69 (Centers for Disease Control and Prevention, "Antigenic Characterization," https://www.cdc.gov/flu/about/professionals/antigenic.htm (visited July 26, 2021)). Mr. Giannantonio's submission was not in accord with the March 23, 2021 Order, which required parties to submit articles only when an expert explained the article's relevance. Order, issued March 23, 2021, at 2. In any event, Mr. Giannantonio did not explain how an article about antigenic characterization helps to support a theory of molecular mimicry between a varicella vaccine and parts of the central nervous system.

In a different section of Mr. Giannantonio's brief, he addresses Idrissova and four other articles. One article reports three cases of chickenpox infection preceding neurologic problems, although not ADEM. Exhibit 59 (D. H. Miller, "Optic neuritis following chickenpox in adults,"233 J Neurol 182 (1986)). In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Human Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports).

The remaining three articles (Marchioni, Lee, and Anikulman) carry more probative value than the Miller case reports. The problem is that the persuasive value of these articles is limited. One article (Marchioni) provides a direct statement: ADEM "is triggered by systemic viral infections or, more rarely, by vaccinations." Exhibit 45 (Enrico Machioni et al., "Acute disseminated encephalomyelitis," 10(4) Curr. Infect. Dis. Rep. 307 (2008)). But, Marchioni does not identify which vaccines and Marchioni does not supply a source for this assertion.

In Lee, the authors stated postvaccinal ADEM has been "associated with" 14 infectious organisms, including varicella. Exhibit 50 (Yun Jin Lee, "Acute disseminated encephalomyelitis in children: differential diagnosis from multiple sclerosis on the basis of clinical course," 54(6) Korean J Pediatr. 234 (2011)) at 235. "Associated with" is not the same as a statement of causation. Doles v. Sec'y of Health & Hum. Servs., 159 Fed. Cl. 241, 248 (2022) (discussing association and causation); Caves v. Sec'y of Health & Hum. Servs., No. 07-443V, 2012 WL 6951286 at *20 (Fed. Cl. Spec. Mstr. Dec. 20, 2012), mot. for rev. denied, 100 Fed. Cl. 119 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012). In addition, while Lee cites one article for this proposition, whether that article supports the assertion for all 14 vaccines is not clear.

Similarly, in Anilkumar, the authors list vaccines against 12 infectious organisms, including varicella, that are associated with ADEM. Exhibit 51 (Arayamparambil C. Anilkumar et al., "Acute Disseminated Encephalomyelitis" 1 (StatsPearls Publishing 2022)). Anilkumar lacks persuasive value for the same reasons as Lee. Neither Marchioni, Lee, nor Anilkumar focused on whether a varicella vaccine can cause ADEM. The passages cited above resemble dicta in a legal opinion. While supportive, they are not particularly helpful.

In response to Mr. Giannantonio's brief, the Secretary argued "simply stating that the vaccine can induce autoimmune reactions via molecular mimicry,

without further evidence, does not suffice to meet petitioner's burden under Althen prong 1." Resp't's Br. at 33. For this proposition, the Secretary cited five cases.[14] In reply, Mr. Giannantonio did not address any of these cases.

The Secretary's position regarding whether evidence makes the theory of molecular mimicry reliable is consistent with the undersigned's evaluation of this issue. See McConnell v. Sec'y of Health & Hum. Servs., No. 18-1051V, 2022 WL 4008238, at *8 (Fed. Cl. Spec. Mstr. Aug. 19, 2022) (stating "[i]dentifying a link between the vaccine and injury enhances the reliability of the theory of molecular mimicry"); Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-22 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (citing appellate cases on molecular mimicry and evaluating detailed evidence regarding whether the flu vaccine can cause rheumatoid arthritis), mot. for rev. denied, 149 Fed. Cl. 448, 464-73 (2020); Heddens v. Sec'y of Health & Hum. Servs., No. 15-734V, 2018 WL 5726991, at *4 (Fed. Cl. Spec. Mstr. Oct. 5, 2018) (memorializing a bench ruling in which petitioner "failed to present empirical evidence to support" the expert's opinion that the HPV vaccine can cause or aggravate multiple sclerosis), mot. for rev. denied, 143 Fed. Cl. 193, 200 (2019) (rejecting an argument that the special master's assessment of molecular mimicry wrongly elevated petitioner's burden of proof).

As the Secretary argues, Dr. Ghacibeh "has not provided evidence of the relevant autoantibodies or identified the homology between an amino acid sequence in the varicella vaccine and a target self-antigen that would support a finding of molecular mimicry as a reliable theory of vaccine causation in this case." Resp't's Br. at 34. Mr. Giannantonio did not refute this characterization.

Therefore, the evidence in this case is not sufficiently robust to meet Mr. Giannantonio's burden on Althen prong 1. However, Idrissova, Marchioni, Lee,

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[14] Regarding evidentiary support for molecular mimicry, the Secretary cites: Monzon v. Sec'y of Health & Hum. Servs., No. 17-1055V, 2021 WL 2711289, at *23 (Fed. Cl. Spec. Mstr. June 2, 2021); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 4072113, at * 50 (Fed. Cl. Spec. Mstr. July 15, 2019); Morgan v. Sec'y of Health & Hum. Servs., No. 15-1137V, 2019 WL 7498665 at *19 (Fed. Cl. Spec. Mstr. Dec. 4, 2019); Johnson v. Sec'y of Health & Hum. Servs., No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018); Yalacki v. Sec'y of Health & Hum. Servs., No. 14-128V, 2019 WL 1061429, at *34 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), mot. for rev. denied, 146 Fed. Cl. 80 (2019).

and Anilkumar could supply a foundation for the presentation of a more developed and more persuasive theory. See Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1368 (Fed. Cir. 2000) (indicating different evidence may produce different results). Given Mr. Giannantonio's failure to present preponderant evidence that C.G. suffered from ADEM and given his failure to present a persuasive theory to show how the varicella vaccine could cause ADEM (assuming C.G. had ADEM), an analysis of the remaining Althen prongs is not necessary.

VI. Disposition on the Papers is Appropriate

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Mr. Giannantonio has had a fair and full opportunity to present his case. After Dr. Ghacibeh presented his initial opinion, Dr. Kruer critiqued it, persuasively pointing out gaps in Dr. Ghacibeh's report. Mr. Giannantonio then presented a rebuttal opinion from Dr. Ghacibeh, which Dr. Kruer again critiqued. Mr. Giannantonio's efforts to address any deficiencies in Dr. Ghacibeh's reports during the briefing process were unpersuasive. Ultimately, Mr. Giannantonio was unable (1) to demonstrate that C.G. suffered from ADEM and (2) to offer a persuasive theory by which the varicella vaccine can cause ADEM. Therefore, a hearing would be unlikely to alter the evidence regarding diagnosis and would not cure the flaws regarding the theory.

VII. Conclusion

Although C.G. has endured a difficult condition for which sympathy is appropriate, the evidence does not show, on a more likely than not basis, that her condition was ADEM. Some treating doctors considered ADEM to be a possibility but turned from a diagnosis of ADEM after C.G.'s MRI did not detect lesions that are commonly found in ADEM. Moreover, even if ADEM had been established as an appropriate diagnosis, the evidence explaining how a varicella vaccine could cause ADEM was unpersuasive.

Accordingly, the Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, available through the Court's website.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master